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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------------|------------------------|
| 10/716,168 | 11/18/2003 | Jifu Zhao | HIGH YIELD THEAFLAVIN | 3876 |
| 7590 DAVID G. HENRY 900 Washington Avenue P.O. Box 1470 Waco, TX 76703-1470 | | | EXAMINER TATE, CHRISTOPHER ROBIN | |
| | | | ART UNIT 1655 | PAPER NUMBER |
| | | | MAIL DATE 11/14/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/716,168 | Applicant(s) ZHAO ET AL. | |
| | Examiner Christopher R. Tate | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1205</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1655

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-10 and 12, in the reply filed on 01 October 2008 is acknowledged. Claims 1-10 and 12 have been examined on the merits.

Claim Objections

Claim 9 is objected to because of the following informalities: There appears to be a transcription error therein - i.e., claim 9 is stated to be an original claim, however the phrase "A comprehensive agent" was not originally claimed (nor is there support within the instant specification for the term "comprehensive"). It would appear that Applicants meant to recite --A chemopreventative agent-- (as originally claimed). [As an aside, please note that if the term "chemopreventative" is inserted into claim 9, an enablement rejection would likely be made in a subsequent Office action given that this term implies an agent capable of preventing any and all cancers - therefore, to hasten prosecution, it is suggested that this term not be used within the claim language itself].

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 6, 8, 10, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1655

Claims 2, 4, 6, 8, and 10 recite the limitation "The product" in line 1 of each. There is insufficient antecedent basis for this limitation in these claims (i.e., each of these claims depend from claims which do not recite the term "product").

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Motoda (JP 57/206391 - full English translation attached), or Ganesan et al. (US 2001/0033880), or Bouwens et al. (US 5,879,730), or Goodsall et al. (US 6,113,965).

The claims are drawn to a product-by-process (having various intended uses) - i.e., a product produced by mixing a measure of green tea polyphenols with a measure of tyrosinase. Based upon the teachings of the instant specification, it is apparent that the product made via the instantly claimed step of mixing green tea polyphenols with tyrosinase results in a black tea

Art Unit: 1655

product containing high levels of various naturally-occurring theaflavins (the pigmented oxidized compounds formed from green tea) therein.

Each of the cited references discloses a black tea product which appears to be identical to the presently claimed product since they are prepared in a manner similar to that instantly claimed/disclosed and/or comprise high levels of theaflavins therein, as discussed in detail below.

Motoda teaches a product produced by mixing a measure of a commercial green tea (which would inherently comprise naturally-occurring polyphenols therein) with a measure of tyrosinase (see entire English translation thereof including page 7 - Embodiment 5).

Ganesan et al. teach a black tea product which is prepared from a measure of macerated green tea leaves (please note that macerated green tea leaves would inherently comprise naturally-occurring polyphenols - such as EC, ECG, EGC, and EGCG, therein) via a process which preferably includes exposure to a measure of an oxidative enzyme such as tyrosinase (or other oxidative enzyme such as polyphenol oxidase or peroxidase) so as to enhance color and flavor of the final black tea product (see entire document including paragraphs [0009] - [0012], [0027] - [0028], and claims including claims 7-8.).

Bouwens et al. teach a black tea product which is prepared via a process which includes the step of exposing a measured solution of green tea (which would inherently comprise naturally-occurring polyphenols - such as EC, ECG, EGC, and EGCG, therein) to a measure of one or more oxidative enzymes such as a polyphenol oxidase (including tyrosinases), laccases, peroxidases, and tannases so as to optimize the intensity of color of the final desired black tea

Art Unit: 1655

product as well as to increase the theaflavin content therein (see entire document including col 1, line 16 - col 3, line 27, and Examples).

Goodsall et al. teach products comprising high levels of black tea theaflavins therein which are prepared via exposing a measure of green tea polyphenols with a measure of an enzyme (i.e., tannase) which is used to cleave the gallate groups from the corresponding green tea polyphenols, whereby the preparatory method can also include further purification of the theaflavins therein (via chromatographic separation) so as to provide for various levels of purified theaflavins within such tea products - such as tea powders (see entire document including col 1, line 4 - col 6, line 34; Examples; claims).

Consequently, the claimed product appears to be anticipated by each of the cited references.

In the alternative, even if the claimed product is not identical to one or more of the referenced products with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced products are likely to inherently possess the same characteristics of the claimed products particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed product would have been obvious to those of ordinary skill in the art within the meaning of USC 103. If necessary, the adjustment of particular conventional working conditions (e.g., substituting a functionally equivalent and/or interchangeable enzyme such as tyrosinase for one or more of the other enzymes disclosed by the cited prior art references: e.g., another polyphenol oxidase, laccase, peroxidase, tannase, in making such a black tea product - especially with regard to those references expressly teaching that a tyrosinase may be employed therein; and/or exposing such green tea products to tyrosinase degradation for a suitable period of time so

Art Unit: 1655

as to provide for various desired levels of pigments and/or theaflavins therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejections above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' product differs and, if so, to what extent, from those disclosed by the cited references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

In addition (with respect to some of the teachings of some of the references cited above), please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

It is further noted that the cited references do not necessarily teach that their black tea/theaflavin-rich products can be used in the manner instantly claimed; however, the intended use of the claimed product does not patentably distinguish the product, *per se*, since such undisclosed use is inherent in the reference products. In order to be limiting, the intended use must create a structural difference between the claimed product and the prior art products. In the

Art Unit: 1655

instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a product in terms of function and the product of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-6 of U.S. Patent No. 6,602,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a black tea product formed by tyrosinase exposure. Further, please note that the instant claims encompass and/or are encompassed by the U.S. '527 claims.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655